

Application No. Applicant(s) VOET, MARTIN A. 10/666.408 Notice of Allowability Examiner **Art Unit** 1656 Chih-Min Kam -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. 1. \square This communication is responsive to 1/30/07. 2. The allowed claim(s) is/are 10-12 and 14-21. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). b) Some* c) None of the: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _ Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. 5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) I including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date __ (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) 6. Interview Summary (PTO-413), Paper No./Mail Date 3. Information Disclosure Statements (PTO/SB/08). 7. X Examiner's Amendment/Comment Paper No./Mail Date 4. Examiner's Comment Regarding Requirement for Deposit 8. X Examiner's Statement of Reasons for Allowance of Biological Material 9. Other ___

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DETAILED ACTION

The Request for Continued Examination (RCE) filed on January 30, 2007 under 37 CFR
1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 10-12 and 14-21 are pending.

Applicants' amendment filed January 30, 2007 is acknowledged, and applicants' response has been fully considered. Claims 10, 17 and 20 have been amended, and new claim 21 has been added. Thus, claims 10-12 and 14-21 are examined.

Withdrawn Claim Rejections - 35 USC § 112

- 3. The previous rejection of claims 10-12 and 14-20 under 35 U. S. C. 112, first paragraph, scope of enablement, is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 4 in the amendment filed January 30, 2007.
- 4. The previous rejection of claims 10-12 and 14-20 under 35 U. S. C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 5 in the amendment filed January 30, 2007.

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Claude L. Nassif on April 5, 2007.

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Examiner's Amendment to the Specification:

Please replace the paragraph at page 1, lines 10-11 with the following paragraph: This application is a continuation in part of U.S. patent application serial number 09/954,610, filed September 17, 2001, now U. S. Patent 6,623,742.

Examiner's Amendment to the Claims:

Claims 15, 16, 18 and 19 have been amended as follows:

- 15. (Currently amended) The method of claim 10, wherein the botulinum toxin is a botulinum toxin type A, B, C, D, E, F or G.
- 16. (Currently amended) The method of claim 10, wherein the botulinum toxin is a botulinum toxin type A.
- 18. (Currently amended) The method of claim 17, wherein the botulinum toxin is a botulinum toxin type A, B, C, D, E, F or G.
- 19. (Currently amended) The method of claim 17, wherein the botulinum toxin is a botulinum toxin type A.

The following is an Examiner's Statement of Reasons for Allowance: The following references appear to be closest art to the claimed invention. Borodic (WO 94/15629) teaches a method of treating myofascial pain syndrome by administering botulinum toxin A to a trigger point, where pressing on the trigger point will trigger the occurrence of pain at a distant location, while the patient with fibromyalgia has the presence of 11 of 18 possible tender points, where pressing on the tender point will produce the pain at this location, thus, the reference does not teach or suggest the treatment of fibromyalgia by administering a botulinum toxin at a first location (e.g., a peripheral location) which is anatomically distinct and/or anatomically distant from a second location, at which second location the patient has a fibromyalgia pain, wherein the first location and the second location are within a same dermatome. Voet (U.S. patent 6,623,742) discloses a method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a peripheral location of a body of a patient afflicted with fibromyalgia, wherein the peripheral location is not a locus of pain, and wherein the locus of pain and the site of administration are located within a same dermatome, and a terminal disclaimer has been filed over the patent. Therefore, the claims are allowable over the art of record.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.

Primary Patent Examiner

CHIH-MIN KAM PRIMARY EXAMINER

CMK

April 5, 2007